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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/713,183	11/14/2003	Dean L. Engelhardt	Enz-52(D2)(C)(D1)	5179
28171	7590	06/02/2006	EXAMINER	
ENZO BIOCHEM, INC. 527 MADISON AVENUE (9TH FLOOR) NEW YORK, NY 10022			SALMON, KATHERINE D	
			ART UNIT	PAPER NUMBER

1634

DATE MAILED: 06/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/713,183

Applicant(s)

ENGELHARDT ET AL.

Examiner

Katherine Salmon

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 91-142 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 91-142 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>12/10/2003</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 1-90 are canceled.
2. An action on the merits of Claims 91-142 is set forth below.

Priority

3. If applicant desires to claim the benefit of a prior-filed application under 35 U.S.C. 120, a specific reference to the prior-filed application in compliance with 37 CFR 1.78(a) must be included in the first sentence(s) of the specification following the title or in an application data sheet. For benefit claims under 35 U.S.C. 120, 121 or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of the applications.

If the instant application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a utility or plant application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or

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120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A benefit claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed benefit claim under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

If the reference to the prior application was previously submitted within the time period set forth in 37 CFR 1.78(a), but not in the first sentence(s) of the specification or an application data sheet (ADS) as required by 37 CFR 1.78(a) (e.g., if the reference was submitted in an oath or declaration or the application transmittal letter), and the information concerning the benefit claim was recognized by the Office as shown by its inclusion on the first filing receipt, the petition under 37 CFR 1.78(a) and the surcharge under 37 CFR 1.17(t) are not required. Applicant is still required to submit the reference in compliance with 37 CFR 1.78(a) by filing an amendment to the first sentence(s) of the specification or an ADS. See MPEP § 201.11.

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Addition of a paragraph in the beginning of the specification describing the relationship of the claimed priority is required.

Abstract

4. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

The abstract of the disclosure is objected to because it exceeds 150 words and uses the phrase "disclose in this invention". Correction is required. See MPEP § 608.01(b).

Specification

5. The disclosure is objected to because of the following: at p. 25, 30-32, and 43 the specification contains a drawing. This should not be included in the text of the specification but should be submitted as a separate figure, including a description of the figure in the specification. See 37 CFR 1.58. Care should be taken not to introduce new matter in the description of the figures. Appropriate correction is required.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

6. Claims 91-100, 112-121, and 133-142 are rejected under 35 U.S.C. 102(b) as being anticipated by Schuster et al. (US Patent 5,169,766 December 8, 1992)

Schuster et al. teaches a method of amplifying a nucleic acid molecule. With regard to Claim 91, Schuster et al. teaches providing a DNA target and mixing the target with nucleoside triphosphates (nucleic acid precursors) (Figure 1 Column 7, lines 60-65). Schuster et al. teaches the proto-primer used can be a RNA sequence (Column 11, lines 47-51). Schuster et al. teaches the use of RNase H to remove RNA from the cDNA (Column 8, lines 7-10). Schuster et al. teaches an mRNA promoter (primer) which is used to extend and make ssRNA (Figure 3). Schuster et al. teaches another primer (DNA) is annealed to the ssRNA and cDNA is copied (Figure 3).

With regard to Claim 112, the claim encompass all the limitations of Claim 91 and the steps of producing a RNA/DNA hybrid as a substrate for RNase H digestion which allows for further primer binding events to occur. Schuster et al. teaches making RNA: DNA hybrid (Column 9, lines 32-33). Schuster et al. teaches the ssRNA (which is the extended promoter) is destroyed by RNase H. Further, any primers which are in the solution but did not primer to the original ssDNA would be destroyed by RNase H, therefore allowing for a reaction solution with only the cDNA that allows the completion

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of another cycle and the production of another cDNA strand identical to the ssDNA template.

With regard to Claim 133, the claim encompass all the limitations of Claim 91 and further that the nucleic acid which is copy is RNA and that a double stranded DNA template is formed in the process. Schuster et al. teaches a method of amplification in which the desired nucleic acid molecules can be RNA (Column 9, lines 52-53). Schuster et al. teaches a method of amplification in which a starting ssRNA analyte is primed in conditions for replication, a double stranded DNA template is produced, and RNase H is used to remove the RNA primers segment to allow the next priming event to occur (Figure 2).

With regard to Claims 92, 113, and 134, Schuster et al. teaches the use of primers which are chemically modified by blocking the 3' terminus using a 3' terminal nucleotide lacking a 3' hydroxyl group (modified nucleotides) (Column 11 lines 60-64).

With regard to Claims 93-94, 114-115, 135-136, and 142, Schuster et al. teaches a promoter primer which has at least 1 noncomplementary nucleotides (Figure 1 2nd step).

With regard to Claims 95, 116, and 137, Schuster et al. teaches that the modified proto-primer can be RNA; therefore it is inherent that an RNA strand would be composed of deoxyribonucleotides (Column 11, lines 47-60).

With regard to Claims 96-98, 117-119, and 138-140, Schuster et al. teaches DNA polymerase (nucleic acid catalyst) include Taq polymerase, Klenow polymerase, E. coli polymerase, and T7 DNA polymerase (Column 7, lines 14-20).

With regard to Claims 99, 120, 141, Schuster et al. teaches mixing the target with nucleoside triphosphates (nucleic acid precursors) (Figure 1 Column 7, lines 60-65).

With regard to Claims 100 and 121, Schuster et al. teaches the use of primers which are chemically modified by blocking the 3' terminus using a 3' terminal nucleotide lacking a 3' hydroxyl group (Column 11 lines 60-64).

7. Claims 91-97, 99-107, 109-118, 120-128, and 130-132 are rejected under 35 U.S.C. 102(b) as being anticipated by Kacian et al. (US Patent 5554516 September 10, 1996).

In the event that priority to prefiled applications is perfected then this rejection would be given under 35 U.S.C. 102(e).

Kacian et al. teaches a method of amplifying a target nucleic acid sequence (Abstract). With regard to Claim 91, Kacian et al. teaches a method of incubating a promoter-primer and a target sequence in DNA priming and nucleic acid synthesizing conditions (ribonucleotide triphosphates and deoxyribonucleotide triphosphates) (nucleic acid precursors) for a period of time to many multiple copies of the target sequence (Column 10 lines 23-33). Kacian et al. teaches the promoter-primer may be altered with ribonucleotides (Column 9, line 15). Therefore the promoter-primer can be RNA: DNA mixture. A primer, which includes a segment of RNA, would be encompassed by the promoter-primer. Kacian et al. teaches using a DNA polymerase

(nucleic acid producing catalyst) (Column 10 line 59). Kacian et al. teaches that generation of target sequence is done using RNase H (Column 4 lines 65-67 and Column 5 lines 1-5).

With regard to Claim 102, the claim encompasses the same steps as Claim 91 except the primer has at least one ribonucleic acid segment and one deoxyribonucleic acid segment. Kacian et al., therefore, teaches all the limitations of Claim 102 because the promoter-primer can have both RNA and a DNA region (Column 9, line 15).

With regard to Claim 112, the claim encompasses the same steps as Claim 91 with the addition that an RNA/DNA hybrid substrate is produced and digested with RNase H to allow additional amplification events. Kacian et al. teaches that the target sequence and the promoter primer sequence will result in a DNA/RNA complex (Column 4, lines 40-45).

With regard to Claim 123, the claim encompasses the same steps as Claim 102 except that the RNA segment is removed by RNase H digestion. Kacian et al. teaches RNase H degrades the RNA portion of RNA: DNA duplex (Column 8, lines 31-34).

With regard to Claims 92, 103, 113, and 124, Kacian et al. teaches the 3' end of the promoter-primer may be modified (Column 7, line 6).

With regard to Claims 93-94, 104-105, 114-115, and 125-126, Kacian et al. teaches a promoter-primer sequence wherein at least 1 nucleotide is noncomplementary (Figure 1).

With regard to Claims 95 and 116, Kacian et al. teaches the promoter-primer may be altered with ribonucleotides (Column 9, line 15).

With regard to Claims 96-97, 106-107, 117-118, and 127-128, Kacian et al. teaches a method using DNA polymerase from E. coli and T7 DNA polymerase (Column 7, lines 60-65).

With regard to Claims 99, 109, 120, and 130, Kacian et al teaches using ribonucleotide triphosphates and deoxyribonucleotide triphosphates (nucleic acid precursors) (Column 10 lines 23-33).

With regard to Claims 100, 110, 121, and 131, Kacian et al. teaches the 3' end of the promoter-primer may be modified (Column 7, line 6). With regard to Claims 101, 111, 122, and 132, Kacian et al. teaches that one modification can be the addition of a phosphorothioate (sulphur heteroatom) (Column 9 lines 17).

8. Claims 91, 93-98, 102, 104-108, 112, 114-119, 123, 125-129, 133, and 135-142 are rejected under 35 U.S.C. 102(b) as being anticipated by Cleuziat et al. (US Patent 5,824,517 October 20, 1998).

In the event that priority to prefiled applications is perfected then this rejection would be withdrawn.

Cleuziat et al. teaches a method for amplifying a specific nucleic acid sequence (Abstract). With regard to Claim 91, Cleuziat et al. teaches a method of using a target nucleic acid (DNA or RNA) isolated from a biological sample (Column 8 lines 6-8). Cleuziat et al. teaches the use of deoxyribonucleotide triphosphates (nucleic acid precursors) (Column 8, lines 22-23). Cleuziat et al. teaches a method of using a chimeric primer, a RNA-type segment and a DNA-type segment (Column 6, lines 57-

65). Cleuziat et al. teaches the use of DNA polymerase (nucleic acid producing catalyst) and RNAase H (Column 8, lines 24-25).

With regard to Claim 102, the claim encompasses the same steps as Claim 91 except the primer has at least one ribonucleic acid segment and one deoxyribonucleic acid segment. Cleuziat et al., therefore, teaches all the limitations of Claim 102 because Cleuziat et al. teaches a method of using a chimeric primer, a RNA-type segment and a DNA-type segment (Column 6, lines 57-65).

With regard to Claim 112, the claim encompass all the limitations of Claim 91 and the steps of producing a RNA/DNA hybrid as a substrate for RNase H digestion which allows for further primer binding events to occur. Cleuziat et al. teaches a method, which involve the step of producing a RNA/DNA heteroduplex (RNA/DNA hybrid) and digesting with RNAase H (Column 12, lines 26-30).

With regard to Claim 123, the claim encompasses the same steps as Claim 102 except that the RNA segment is removed by RNase H digestion. Cleuziat et al. teaches RNAase H digests the RNA of the RNA/DNA heteroduplex (Column 12, lines 26-30).

With regard to Claim 133, the claim encompass all the limitations of Claim 91 and further that the nucleic acid which is copy is RNA and that a double stranded DNA template is formed in the process. Cleuziat et al. teaches the amplification of RNA (Abstract). Cleuziat et al. teaches double strands of DNA are obtained (Column 11, lines 66-67).

With regard to Claims 93-94, 104-105, 114-115, 125-126, 135-136, and 142, Cleuziat et al. teaches a primer with at least one nucleotide that is noncomplementary to the target (Figure 1, A1 step 2).

With regard to Claims 95, 116, and 137, Cleuziat et al. teaches the use of deoxyribonucleotides (Column 8 lines 22-23).

With regard to Claims 96-98, 106-108, 117-119, 127-129 and 138-140, Cleuziat et al. teaches the use of catalysts such as klenow and Taq polymerase (Column 9 line 33 and Column 10 line 15-16).

With regard to Claims 99, 109, 120, 130, and 141, Cleuziat et al. teaches the use of deoxyribonucleotide triphosphates (nucleic acid precursors) (Column 8, lines 22-23).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 101 and 122 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schuster et al. (US Patent 5,169,766 December 8, 1992) in view of Skerra (Nucleic Acids Research 1992 Vol. 20 p. 3551).

Schuster et al. teaches a method of amplifying a nucleic acid molecule. Schuster et al. teaches providing a DNA target and mixing the target with nucleoside triphosphates (nucleic acid precursors) (Figure 1 Column 7, lines 60-65). Schuster et al. teaches the proto-primer used can be a RNA sequence (Column 11, lines 47-51). Schuster et al. teaches the use of RNase H to remove RNA from the cDNA (Column 8, lines 7-10). Schuster et al. teaches an mRNA promoter (primer) which is used to extend and make ssRNA (Figure 3). Schuster et al. teaches another primer (DNA) is annealed to the ssRNA and cDNA is copied (Figure 3).

Schuster et al. teaches making RNA: DNA hybrid (Column 9, lines 32-33). Schuster et al. teaches the ssRNA (which is the extended promoter) is destroyed by RNase H. Further, any primers which are in the solution but did not primer to the original ssDNA would be destroyed by RNase H, therefore allowing for a reaction solution with only the cDNA that allows the completion of another cycle and the production of another cDNA strand identical to the ssDNA template.

Schuster et al., however, does not teach primers modified by heteroatoms comprised of nitrogen or sulfur and chemically modified primers comprised of nucleoside triphosphates.

Skerra teaches a method of using phosphorothioate primers in an amplification method (Abstract). With regard to Claims 96-97, Skerra teaches the modification of primers by the addition of a single phosphorothioate bond (heteroatom of sulfur) at the first 3' terminal internucleotide linkage during synthesis of the oligodeoxynucleotide (p. 3552 1st column last paragraph). Skerra teaches that the phosphorothioate bond is much less favored substrate to nuclease activity than the naturally occurring phosphodiester bond (P. 3552 1st column last sentence and 2nd column 1st sentence).

Therefore it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Schuster et al., to use the phosphorothioate primers as taught by Skerra. The ordinary artisan would have been motivated to modify the method of Schuster et al, because Skerra teaches the use of phosphorothioate primers would avoid the lower PCR yield and non-specific side products resulting from 3' terminal editing of the primer molecule by protecting the oligodeoxynucleotide from a 3' terminal exonucleolytic attack (p. 3553 2nd column last paragraph).

11. Claims 98, 108, 119, and 129 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kacian et al. (US Patent 5554516 September 10, 1996) in view of Schuster et al. (US Patent 5,169,766 December 8, 1992).

Kacian et al. teaches a method of amplifying a target nucleic acid sequence (Abstract). Kacian et al. teaches a method of incubating a promoter-primer and a target sequence in DNA priming and nucleic acid synthesizing conditions (ribonucleotide triphosphates and deoxyribonucleotide triphosphates) (nucleic acid precursors) for a period of time to many multiple copies of the target sequence (Column 10 lines 23-33). Kacian et al. teaches the promoter-primer may be altered with ribonucleotides (Column 9, line 15). Therefore the promoter-primer can be RNA: DNA mixture. A primer, which includes a segment of RNA, would be encompassed by the promoter-primer. Kacian et al. teaches using a DNA polymerase (nucleic acid producing catalyst) (Column 10 line 59). Kacian et al. teaches that generation of target sequence is done using RNase H (Column 4 lines 65-67 and Column 5 lines 1-5).

Kacian et al. teaches the promoter-primer can have both RNA and a DNA region (Column 9, line 15).

Kacian et al. teaches that the target sequence and the promoter primer sequence will result in a DNA/RNA complex (Column 4, lines 40-45).

Kacian et al. teaches RNase H degrades the RNA portion of RNA: DNA duplex (Column 8, lines 31-34).

Kacian et al., however, does not teach the use of Taq DNA polymerase. Schuster et al. teaches a method of amplifying a nucleic acid molecule. With regard to Claims 98, 108, 119, and 129, Schuster et al. teaches providing a DNA target and mixing the target with nucleoside triphosphates. Schuster et al. teaches DNA

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polymerase includes Taq polymerase, Klenow polymerase, E. coli polymerase, and T7 DNA polymerase (Column 7, lines 14-20).

Therefore it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Kacian et al., to use Taq Polymerase as taught by Schuster et al. The ordinary artisan would have been motivated to modify the method of Kacian et al., because Schuster et al. teaches the use of Taq Polymerase is a preferred DNA polymerase (Column 7, lines 14-15). The ordinary artisan would want to use the most preferred polymerase for incorporating nucleoside triphosphates to extend the nucleic acid in order to perform an amplification method which can produce many copies of a target sequence.

Double Patenting

12. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

13. Claims 91-101 provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 91-99 of copending Application No. 10/718391. Although the conflicting claims are not identical, they are not patentably distinct from each other because Claim 91-101 of the instant application describes the same method steps as Claim 91-99 of application 10/718391. Both applications are drawn to a method of producing copies of a specific nucleic acid by providing a nucleic acid sample, contacting it with unmodified nucleic acid precursors and modified RNA primers. Both applications use a catalyst. Both applications modify primers using heteroatoms comprising nitrogen or sulfur. Both applications claims are drawn to primers, which comprise about 1 to about 200 noncomplementary nucleotide or nucleotide analogs. The primers of the instant application are encompassed by the genus of generic primers claimed by 10/718391. The specification of 10/718391 defines a primer as DNA, RNA, or DNA:RNA, therefore the claims of 10/718391 are drawn to a method using a genus of primers which include the RNA primer and the DNA:RNA primer of the instant application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

14. No claims are allowable over the cited prior art.

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15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Katherine Salmon whose telephone number is (571) 272-3316. The examiner can normally be reached on Monday-Friday 8AM-430PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Katherine Salmon 5/25/2006

Katherine Salmon
Examiner
Art Unit 1634

J. Goldberg
JEANINE A. GOLDBERG
PRIMARY EXAMINER
5/26/06